

MAY 28 2004

K040891

510(K) SUMMARY

Submitter: KLS-Martin, L.P.
11239-1 St. Johns Industrial Parkway South
Jacksonville, FL 32246
Phone: 904-641-7746
Fax: 904-641-7378

Contact Person: Jennifer Damato
Director RA/QA

Date of Summary: April 5, 2004

Device Name: KLS-Martin Ortho Anchorage System (Plates)

Trade Name: Ortho Anchorage System

Common Name: Bone Plate

**Classification
Name and Number:** Endosseous Implant (CFR 872.3640)

Regulatory Class: Class III

Predicate Devices: KLS-Martin Micro Osteosynthesis System
(1.5mm) (K944565)

Nobel Biocare Onplant Orthodontic System
(K980460)

**Device
Description:** The KLS-Martin Ortho Anchorage System includes several different designs of titanium plates.

Intended Use: The KLS-Martin Ortho Anchorage System is intended to be surgically placed in the mouth for use as an anchor for orthodontic procedures.

Technological Characteristics:

Similarities to Predicate

Plates are identical in materials and manufacturing process to the KLS-Martin Micro Osteosynthesis System (1.5mm) (K944565).

Differences to Predicate

The KLS Martin Osteosynthesis System (1.5mm) (K944565) is intended for bone fixation across fractures or osteotomies. The KLS Martin Ortho Anchorage System (Plates) is designed to aid in dental movement by providing a rigid skeletal fixation point. The KLS Martin Ortho Anchorage System (Plates) are different in shape to The KLS Martin Osteosynthesis System (1.5mm) (K944565).

The Nobel Biocare Onplant Orthodontic System (K980460) is a single threaded implant utilized as an anchor for orthodontic procedures in the palatal region. The KLS Martin Ortho Anchorage System (Plates) are titanium plates that are fixated with titanium screws utilized as an anchor for orthodontic procedures in the palatal, maxilla or mandible region.

Substantial Equivalence:

The KLS-Martin Ortho Anchorage System is substantially equivalent in application to the KLS-Martin Micro Osteosynthesis System (1.5mm) (K944565)

The KLS-Martin Ortho Anchorage System is substantially equivalent in indications for use to the Nobel Biocare Onplant Orthodontic System (K980460)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 2004

Jennifer Damato
KLS-Martin L.P.
Director Regulatory Affairs Quality Assurance
11239-1 St. John Industrial Parkway South
Jacksonville, Florida 32246

Re: K040891
Trade/Device Name: KLS Martin Ortho Anchorage System (Plates)
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: May 12, 2004
Received: May 14, 2004

Dear Ms. Damato:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

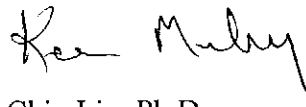
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



for

Chiu Lin, Ph.D

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: KLS Martin Ortho Anchorage System (Plates)

Indications For Use:

The KLS-Martin Ortho Anchorage System (Plates) are implants intended to be surgically placed in the mouth for use as an anchor for orthodontic procedures in patients.


Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040891

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